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K 041284

510(k) Summary

Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination

Indications for use

MediCult IVM®System including Vial 1, LAG Medium and Vial 2 , IVM®Medium.

The LAG Medium is for incubation of immature oocytes and the IVM®Medium is a basal medium for maturing immature oocytes of infertile women undergoing in vitro fertilization who for medical reasons can not undergo conventional ovarian stimulation using drugs. .

Stability, cytotoxicity- and biocompatibility testing

The IVM®System has been stability tested and a shelf life of 8 weeks from shipment date is recommended. As the MediCult IVM®System is not in contact with the patient, biocompatibility studies have not been performed.

Product testing controls

- Sterility
- pH
- Osmolality
- Endotoxin ≤ 0.1 EU/ml (USP, Ph.Eur.)
- Mouse Embryo Assay, (one cell assay, Blastocyst rate > 80 %)

For each batch a Certificate of Analysis with the results of the above tests is available.

Clinical Documentation

MediCult IVM® System is a sequential media system including LAG Medium and IVM®Medium which has been developed specifically to support maturation in-vitro of immature oocytes.

The composition of the LAG medium is similar to the composition of Universal IVF Medium. Like the Universal IVF Medium the IVM®Medium contains physiological salts and nutritients but differs from this medium by also containing vitamins, amino acids and nucleotides and by being free from human serum albumin.

MediCult IVM®System is indicated for pre-incubation and maturing of immature oocytes and is substantially equivalent to MediCult's Universal IVF Medium (K 991279) indicated for preparation of mature oocytes.

The MediCult IVM®System has been tested in two studies by Prof. Svend Lindenberg at Herlev University Hospital in Denmark and by Dr. Anna-Maria Suikkara at Väestöliitio, the Infertility Clinic of the Family Federation of Finland in Helsinki, Finland. The pregnancy rates obtained after retrieval of immature oocytes have been compared to the pregnancy rates obtained after retrieval of mature oocytes. The pregnancy rates per embryo transfer obtained using MediCult IVM®System of the immature oocytes prior to fertilisation were slightly lower than the results obtained using mature

oocytes and the Universal IVF Medium. However, the IVM®System is advantageous for the woman as she compared to classic IVF/ICSI avoids both the hormone stimulation and thereby the side effects that are related to the hormones and the many visits to the fertility clinic.

It can therefore be concluded that the MediCult IVM®System and the Universal IVF Medium (K991279) both are effective for preparing immature and mature oocytes, respectively, for insemination and that the MediCult IVM® System is substantially equivalent to the Universal IVF Medium (K991279).

During our studies there have been no registered complaints and no evidence that the product has been the cause of any serious adverse events in connection with its intended use.

Thus based on the clinical data presented and our experience with the MediCult IVM®System product, we feel that the safety and effectiveness of the product for its intended use is shown in the present submission and the products are substantially equivalent to the predicated device MediCult's Universal IVF Medium (K991279).

Prepared and Submitted by:

Oct. 08, 2004

Ronald G. Leonardi, Ph.D. Date
President
R & R REGISTRATIONS
P.O. Box 262069 San Diego, Ca 92196
858-586-0751

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2004

MediCult a/s
% Ronald G. Leonardi, Ph.D.
President
R & R Registrations
P.O. Box 262069
SAN DIEGO CA 92196-2069

Re: K041284
Trade/Device Name: MediCult IVM® System
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: August 30, 2004
Received: September 31, 2004

Dear Dr. Leonardi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) **K041284**

Device Name: MediCult IVM® System

INDICATIONS FOR USE:

Vial 1: The LAG Medium is for pre-incubation of immature oocytes.

Vial 2: IVM® Medium is a basal medium for maturing immature oocytes with supplements

"The LAG medium is for pre-incubation of immature oocytes and the IVM Medium is a basal medium for maturing immature oocytes of infertile women undergoing in vitro fertilization who for medical reasons can not undergo conventional ovarian stimulation using drugs."

(PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041284